

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: G Surgical Co., Ltd.
152 Soi Ramkhamhaeng 138
Sapansung, Bangkok
Thailand

JUN 27 2008

Device: GPS™, G Surgical Pedicle System,

Classification Name: Pedicle Screw Spinal System (21 CFR 888.3070)

Intended Use: The GPS™, G Surgical Pedicle System is a pedicle screw based spinal fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the GPS™, G Surgical Pedicle System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the GPS™, G Surgical Pedicle System is indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

Device Description: The GPS™, G Surgical Pedicle System is a top-loading anterior / posterior spinal fixation system which consists of Mono and Polyaxial pedicle screws, rods, set screws, connectors, and a transverse (cross) linking mechanism. The GPS™ implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The GPS™, G Surgical Pedicle System can be used in both the anterior and posterior planes providing unilateral and bilateral modes of fixation.

The GPS™, G Surgical Pedicle System design allows adjustment in both the sagittal and coronal planes permitting screw placement according to the best possible anatomic (spinal) location and orientation. This is accomplished by means of a preassembled washer in the housing component between screw and the rod which tightens against the head of the pedicle screw upon connection of the set screw with the rod.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the GPS™, G Surgical Pedicle System implants.

Potential Risks: The potential risks associated with this device are the same as with any spinal fixation device. These include, but are not limited to:

Blood vessel damage
Deformity of the joint
Cardiovascular disorders
Component Failure
Implant loosening/migration

Bone fracture
Soft tissue complications
Delayed wound healing
Metal sensitivity
Fracture of the components

Nerve damage
Infection
Hematoma
Nerve impingement
Excessive wear



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

G Surgical Co. Ltd
% Mr. Donald Grafton
Managing Director
152 Soi Ramkhamhaeng 138
Sapansung, Bangkok 10240
Thailand

JUN 27 2008

Re: K081041
Trade/Device Name: GPSTTM, G Surgical Pedicle System
Regulation Number: CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: April 10, 2008
Received: April 11, 2008

Dear Mr. Grafton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Donald Grafton

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081041
INDICATIONS FOR USE

Device Name GPS™, G Surgical Pedicle System

Indications for Use: The GPS™, G Surgical Pedicle System, is a pedicle screw based spinal fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use X AND/OR Over the Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number

K081041